UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NICHOLAS THOMAS and ALAN WAGGONER

Appeal No. 2006-0670
Application No. 09/914,603

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-13 and 15-17. Claim 1 is representative of the claims on appeal, and reads as follows:

1. A method of detecting and analyzing differences between nucleic acids from two sources, which method comprises:

a. providing the nucleic acids from two sources as labeled probes wherein the nucleic acids from each source are labeled with a distinct marker;

b. forming a mixture of the labeled probes with pooled reagents of at least two reagents wherein each of the pooled reagents comprises a population of beads carrying a polynucleotide target of known sequence, the polynucleotide target of any one of the pooled reagents being different from the target of any

other of the pooled reagents and the beads of any one of the pooled reagents being distinguishable from the beads of any other of the pooled reagents by flow cytometry;

c. incubating the mixture under conditions to promote specific hybridization between probes and targets; and

d. analyzing beads in the mixture by flow cytometry to determine the identity of each bead and to quantify the relative abundance of each target sequence in the two sources.

The examiner relies upon the following references:

Cocuzza et al. (Cocuzza)	5,484,701	Jan. 16, 1996
Beattie et al. (Beattie)	6,268,147 B1	Jul. 31, 2001

Claims 1-4, 6-13 and 15-17 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Beattie. In addition, claim 5 stands rejected under 35 U.S.C § 103(a) as being obvious over the combination of Beattie and Cocuzza. After careful review of the record and consideration of the issues before us, we affirm.

DISCUSSION

Claims 1-4, 6-13 and 15-17 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Beattie.

We initially note that appellants do not argue the claims separately, thus they are deemed to stand or fall together. See In re Dance, 160 F.3d 1339, 1340 n.2, 48 USPQ2d 1635, 1636 n.2 (Fed. Cir. 1998) (noting that dependent claims not argued separately on the merits rise or fall with the independent claim to which they relate). We thus focus our analysis on independent claim 1.

Beattie is cited for teaching "a method of nucleic acid analysis using tandem hybridization on color-coded microspheres and flow cytometric detections," citing Example 18. Examiner's Answer, page 4. Beattie teaches further that "nucleic acid analyte is annealed with a labeled stacking probe of sequence and length designed to bind to a unique position with the analyte nucleic acid (col. 38, lines 60-64)." Id. According to the examiner, Beattie teaches that "[f]or genotyping and mutation analysis, allele specific capture probes are hybridized with genomic DNA or mixture of PCR products, preannealed with a mixture of stacking probes," wherein "[t]he quantity of label associated with each color-coded bead is quantitatively determined using flow cytometry with spectral analysis of individual beads streaming past the detector window (col. 39, lines 5-10)." Id. Beattie is also relied upon for teaching the use of dual labels, one for use with a reference sample and the other with a test sample, and that when the two samples are hybridized with capture probes immobilized on color coded beads, the relative binding of the two labels to each color-coded bead will provide a transcriptional profile of the two samples simultaneously. See id. at 5.

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that Beattie discloses every limitation of appealed claim 1, and the rejection is affirmed.

Appellants contend that Beattie does not anticipate the claimed invention, as "[t]he method of Beattie requires hybridization of three molecules, (a) a labeled stacking probe, (b) a probe on the bead, and (c) a nucleic acid to be analyzed." Appeal Brief, page 5. Appellants assert that Beattie thus fails to disclose a method comprising a step of "providing the nucleic acids from two sources as labeled probes," instead teaching the use of a labeled stacking probe for detection of hybridization. Id. Appellants' arguments are not found to be convincing, as the labeled stacking probe of Beattie reads on the label that is used to label the nucleic acids from two sources.

Example 18 of Beattie states that:

> For genotyping and mutational analysis, allele-specific capture probes (each associated with a different color-coded bead) are hybridized with genomic DNA (or mixture of PCR products) preannealed with a mixture of stacking probes (binding to the target DNA adjacent to a set of polymorphic or mutation-bearing sites). The quantity of label associated with each color-coded bead (quantitatively determined using flow cytometry with spectral analysis of individual beads streaming past the detector window) will reveal the allele status at each marker or mutational site analyzed. If expressed sequence-specific stacking and capture probes are used with mRNA or cDNA analyte (as described in previous examples of oligonucleotide array hybridization), the relative level of label (from stacking probes) bound to each color-coded bead will provide a gene expression (transcriptional) profile. The stacking probe must be labeled with a tag that is distinguishable from the spectral properties of color-coded beads. If dual labels are used (one used in preannealing with a "reference" sample and another used in preannealing with a "test" sample, and the two samples are hybridized together with the mixture of color-coded beads, the relative binding of the two labels (from stacking probes) to each color-coded bead will reveal the two transcriptional profiles simultaneously.

Column 39, lines 1-24.

The stacking probe in the method of Beattie thus acts as the label that is used to label the nucleic acids from two sources. Beattie specifically teaches the method in which dual labels are used, and thus teaches method step (a) of claim 1. Note that the claim merely requires that the nucleic acids from two sources be provided as labeled probes, but does not specify how the probes are labeled.

Beattie teaches that the samples are hybridized together, and also teaches that capture probes associated with color coded beads are used, and that the quantity of label associated with each color-coded bead may be determined using flow cytometry, thus teaching method steps (b), (c) and (d) of claim 1. Thus, Beattie anticipates the method of claim 1, and the rejection is affirmed.

Claim 5 stands rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Beattie and Cocuzza.

As appellants merely argue that there is a fundamental difference between the current invention and the invention of Beattie, see Appeal Brief, page 6, this rejection is affirmed for the reasons set forth above.

CONCLUSION

Because we find that the examiner has set forth a prima facie case of anticipation, the rejection of claims 1-4, 6-13 and 15-17 under 35 U.S.C. § 102(e) over Beattie is affirmed. Because appellants do not separately argue the patentability of the rejection of claim 5 under 35 U.S.C. § 103(a) over the combination of Beattie and Cocuzza, we affirm that rejection as well.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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Toni R. Scheiner) BOARD OF PATENT
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